# **Complete Summary**

#### **GUIDELINE TITLE**

Practice parameters for the prevention of venous thromboembolism.

## **BIBLIOGRAPHIC SOURCE(S)**

Stahl TJ, Gregorcyk SG, Hyman NH, Buie WD, Standards Practice Task Force of The American Society of Colon and Rectal. Practice parameters for the prevention of venous thrombosis. Dis Colon Rectum 2006 Oct;49(10):1477-83. [51 references] PubMed

## **GUIDELINE STATUS**

This is the current release of the guideline.

This guideline updates a previous version: Practice parameters for the prevention of venous thromboembolism. The Standards Task Force of the American Society of Colon and Rectal Surgeons. Dis Colon Rectum 2000 Aug;43(8):1037-47.

## \*\* REGULATORY ALERT \*\*

## FDA WARNING/REGULATORY ALERT

**Note from the National Guideline Clearinghouse**: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

• February 28, 2008, Heparin Sodium Injection: The U.S. Food and Drug Administration (FDA) informed the public that Baxter Healthcare Corporation has voluntarily recalled all of their multi-dose and single-use vials of heparin sodium for injection and their heparin lock flush solutions. Alternate heparin manufacturers are expected to be able to increase heparin production sufficiently to supply the U.S. market. There have been reports of serious adverse events including allergic or hypersensitivity-type reactions, with symptoms of oral swelling, nausea, vomiting, sweating, shortness of breath, and cases of severe hypotension.

# **COMPLETE SUMMARY CONTENT**

\*\* REGULATORY ALERT \*\*

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IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
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# **SCOPE**

# **DISEASE/CONDITION(S)**

Venous thrombosis

## **GUIDELINE CATEGORY**

Prevention Risk Assessment

## **CLINICAL SPECIALTY**

Colon and Rectal Surgery Preventive Medicine

#### **INTENDED USERS**

Health Care Providers Patients Physicians

## **GUIDELINE OBJECTIVE(S)**

To provide practice parameters for the prevention of venous thrombosis

#### **TARGET POPULATION**

Patients undergoing surgery of the colon and rectum

## INTERVENTIONS AND PRACTICES CONSIDERED

- 1. Assessment of risk category (low, moderate, high, or highest)
- 2. Physical prophylactic measures including early ambulation, elastic stockings, and intermittent pneumatic compression (IPC) devices
- 3. Chemical prophylaxis including low-dose unfractionated heparin (LDUH) or low-molecular-weight heparin (LMWH)

#### **MAJOR OUTCOMES CONSIDERED**

- Efficacy of venous thromboembolism (VTE) prophylaxis
- Risk and rates of venous thromboembolism
- Adverse effects associated with chemical prophylaxis

## **METHODOLOGY**

# METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

## **DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE**

Not stated

#### NUMBER OF SOURCE DOCUMENTS

Not stated

# METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

#### RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

#### **Levels of Evidence**

- I. Meta-analysis of multiple well-designed, controlled studies; randomized trials with low false-positive and low false-negative errors (high power)
- II. At least one well-designed experimental study; randomized trials with high false-positive or high false-negative errors or both (low power)
- III. Well-designed, quasi-experimental studies, such as nonrandomized, controlled, single-group, preoperative-postoperative comparison, cohort, time, or matched case-control series
- IV. Well-designed, nonexperimental studies, such as comparative and correlational descriptive and case studies
- V. Case reports and clinical examples

## METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses Systematic Review

## **DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE**

Not stated

## METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

## RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

## **Grades of Recommendations**

- A. Evidence of Type I or consistent findings from multiple studies of Type II, III, or IV
- B. Evidence of Type II, III, or IV and generally consistent findings
- C. Evidence of Type II, III, or IV but inconsistent findings
- D. Little or no systematic empirical evidence

## **COST ANALYSIS**

In numerous well-performed studies and several meta-analyses comparing the efficacy of venous thromboembolism (VTE) prophylaxis between low-molecular-weight-heparin (LMWH) and low-dose-unfractionated heparin (LDUH) for VTE prophylaxis, unfractionated heparin has been shown to be equally effective and more cost-effective.

## **METHOD OF GUIDELINE VALIDATION**

Not stated

## **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

Not stated

## **RECOMMENDATIONS**

## **MAJOR RECOMMENDATIONS**

The levels of evidence (I-V) and the grades of recommendations (A-D) are defined at the end of the "Major Recommendations" field.

#### **Treatment Recommendations**

- Patients undergoing anorectal procedures who are younger than 40 years of age and have no additional risk factors (see Table 1 in the original guideline document for a list of risk factors) for venous thromboembolism (VTE) require no specific prophylaxis. Level of Evidence: V; Grade of Recommendation:
- 2. Patients undergoing anorectal procedures who are older than 40 and/or have additional risk factors for VTE should be considered for prophylaxis on a caseby-case basis. **Level of Evidence: V; Grade of Recommendation: D**

Patients in the moderate-risk to high-risk group (see original guideline document for a description of each of the four risk categories: low-risk, moderate-risk, high-risk, and highest risk) are appropriately considered for prophylaxis based on the number of risk factors, the length and magnitude of the planned surgery, and the risk of bleeding. The appropriate means of prophylaxis would be mechanical compression or heparin (low-dose unfractionated heparin [LDUH] or low-molecular-weight heparin [LMWH]). Because of the frequent outpatient nature of this type of surgery and the

potential for bleeding in many anorectal procedures, mechanical prophylaxis may be preferable in most cases.

3. Patients in the moderate-risk to high-risk categories for VTE undergoing abdominal surgery should receive prophylaxis with LDUH or LMWH. Patients at risk for bleeding may receive mechanical prophylaxis instead. **Level of Evidence: I; Grade of Recommendation: A** 

Mechanical methods may be chosen in patients in whom the risk of bleeding is judged to outweigh the benefit of prophylactic heparin.

4. Patients in the highest-risk category for VTE should receive both mechanical and heparin prophylaxis. Level of Evidence: I; Grade of Recommendation: A

In this high-risk group, mechanical prophylaxis adds further protection compared with heparin alone.

- Patients undergoing laparoscopic colorectal procedures should receive VTE prophylaxis according to the same risk assessment that would be applicable for the same surgery performed as an open procedure. Level of Evidence: V; Grade of Recommendation: D
- 6. Patients who have undergone major cancer surgery may benefit from posthospital prophylaxis with LMWH. Level of Evidence: II; Grade of Recommendation: C

The optimum duration of VTE prophylaxis is currently unknown. Although most deep vein thrombosis (DVT) occurs within the first week or two after surgery, VTE complications, including pulmonary embolism (PE), can occur beyond that time frame. These findings combined with shrinking hospital stays have generated an interest in the appropriate duration of VTE prophylaxis. There is evidence that in cancer-surgery patients, continued prophylaxis for two to three weeks after discharge reduces the incidence of asymptomatic DVT.

## **Definitions**

## **Levels of Evidence**

- I. Meta-analysis of multiple well-designed, controlled studies; randomized trials with low false-positive and low false-negative errors (high power)
- II. At least one well-designed experimental study; randomized trials with high false-positive or high false-negative errors or both (low power)
- III. Well-designed, quasi-experimental studies, such as nonrandomized, controlled, single-group, preoperative-postoperative comparison, cohort, time, or matched case-control series
- IV. Well-designed, nonexperimental studies, such as comparative and correlational descriptive and case studies
- V. Case reports and clinical examples

# **Grades of Recommendations**

- A. Evidence of Type I or consistent findings from multiple studies of Type II, III, or IV
- B. Evidence of Type II, III, or IV and generally consistent findings
- C. Evidence of Type II, III, or IV but inconsistent findings
- D. Little or no systematic empirical evidence

## **CLINICAL ALGORITHM(S)**

None provided

## **EVIDENCE SUPPORTING THE RECOMMENDATIONS**

## TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations" field).

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

#### **POTENTIAL BENEFITS**

Appropriate use of practice parameters for the prevention of venous thrombosis

## **POTENTIAL HARMS**

- Low-dose unfractionated heparin (LDUH) is associated with only a modest increase in minor bleeding complications, such as wound hematoma
- A potential danger has been associated with the use of heparin prophylaxis in conjunction with spinal or epidural anesthesia. The most serious potential complication is the development of a perispinal hematoma, which can lead to spinal cord ischemia and paraplegia. This complication has been reported with both LDUH and LMWH, but more so with LMWH. Refer to the original guideline document for detailed instructions on the use of heparin prophylaxis in conjunction with spinal or epidural anesthesia.

# **QUALIFYING STATEMENTS**

## **QUALIFYING STATEMENTS**

These guidelines are inclusive and not prescriptive. Their purpose is to provide information on which decisions can be made, rather than dictate a specific form of treatment. It should be recognized that these guidelines should not be deemed inclusive of all proper methods of care or exclusive of methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding the propriety of any specific procedure must be made by the physician in light of all of the circumstances presented by the individual patient.

## **IMPLEMENTATION OF THE GUIDELINE**

## **DESCRIPTION OF IMPLEMENTATION STRATEGY**

An implementation strategy was not provided.

# INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

## **IOM CARE NEED**

Staying Healthy

#### **IOM DOMAIN**

Effectiveness

## **IDENTIFYING INFORMATION AND AVAILABILITY**

# **BIBLIOGRAPHIC SOURCE(S)**

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# **ADAPTATION**

Not applicable: The guideline was not adapted from another source.

# **DATE RELEASED**

2000 Aug (revised 2006 Oct)

# **GUIDELINE DEVELOPER(S)**

American Society of Colon and Rectal Surgeons - Medical Specialty Society

# **SOURCE(S) OF FUNDING**

American Society of Colon and Rectal Surgeons

## **GUIDELINE COMMITTEE**

Standards Practice Task Force of the American Society of Colon and Rectal Surgeons

## **COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE**

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## FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

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## **GUIDELINE AVAILABILITY**

Electronic copies: Available in Portable Document Format (PDF) from the American Society of Colon and Rectal Surgeons (ASCRS) Web site.

Print copies: Available from the ASCRS, 85 W. Algonquin Road, Suite 550, Arlington Heights, Illinois 60005.

## **AVAILABILITY OF COMPANION DOCUMENTS**

None available

#### **PATIENT RESOURCES**

None available

## **NGC STATUS**

This summary was completed by ECRI on February 13, 2001. The information was verified by the guideline developer on May 9, 2002. This NGC summary was updated by ECRI Institute on May 30, 2007. This summary was updated by ECRI Institute on March 14, 2008 following the updated FDA advisory on heparin sodium injection.

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